TESTIMONY BY HOWARD M. SANDLER, M.D.
Before the
Oversight and Investigation Subcommittee
Community Opportunity Subcommittee
Of the
One Hundred Seventh U.S. Congress
House of Representatives
Committee on Financial Services

July 18, 2002

Background

Physicians specializing in occupational and environmental medicine are increasingly being called upon to investigate complaints associated with workplace and residential indoor air quality and suspected exposure to microbiological agents.

Indoor air quality concerns often focus on the presence of viruses, bacteria, molds and the chemicals (MVOCs) and toxins that some produce, known as mycotoxins.

There are a variety of molds found in outdoor and indoor environments. Typically, the outdoor levels will exceed those found indoors. As might be expected, the levels of molds will vary by geographic location and weather (e.g. higher with periods of rain). Species of various molds frequently identified in the outdoors, homes and buildings include those of Penicillium, Cladosporium, Stachybotrys and Aspergillus. The relative amounts of each fungi species in outdoor vs. indoor air, however, are not frequently found to be the same. Aflatoxin, a carcinogen produced by the Aspergillus species, is probably the most recognized mycotoxin. Molds and the chemical products they produce, mycotoxins and microbial organic compounds (MVOCs) are ubiquitous to our environment. Mold is not nationally regulated currently with the exception of aflatoxins. Aflatoxins are found in peanut butter, peanuts and wheat. Aflatoxin ingestion has been correlated with hepatocellular carcinoma (liver cancer).

Another microbiologic, Legionella pneumophila, was first identified as the cause of Legionnaires' disease in 1976. The annual number of Legionnaires' disease cases in the United States is estimated at 10,000 to 25,000. The bacteria survive principally in water, and to a lesser extent in soil. Legionnaires' has been traced to drinking water, bath water, whirlpools, hot tubs, and medication nebulizers.

Mycotoxicosis is a disease associated with extensive exposure to mycotoxins. Reported serious health effects of mycotoxicosis include immunosupression, as well as estrogenicity, hepatoxicity, mutagenicity, nephroptoxicity, teratogenicty, neurotoxicity, and carcinogenicity. However, while such effects have been identified, the strength of the associations, occurrences in human populations, quality of the studies and applicability to airborne workplace and residential exposures remain to be clarified. Mycotoxins are in many food products including meats, spices, seeds, nuts, cereals, beer, grains, milk and dairy products, and fruits and vegetables. Tobacco also contains mycotoxins.

In addition, certain populations are considered to be hypersusceptible to microbiologic diseases. These people include people with AIDS and other immunocompromising conditions such as, kidney dialysis patients, organ transplant recipients, cancer patients, smokers, and individuals undergoing steroid treatment.

In the past decade, Stachybotrys, a mold proposed to be highly toxic, also has gained significant attention. The presence of Stachybotrys species has heightened concerns about of the presence of mycotoxins in indoor environments. Stachybotrys produces trichothecenes, stachybocine and other mycotoxins. To date, findings associated with Stachybotrys have been primarily based on case reports and made in the absence of pathological testing or control of confounding factors.

True stachybotryotoxicosis first associated with the ingestion of highly contaminated food products, especially in Russia, has been described as a severe disorder occurring over several weeks. The clinical picture has been reported as being similar to radiation poisoning.

Molds will grow in humid environments, especially where standing water exists, such as flat roofs, damp filters and HVAC system components. Water damage from leaking roofs or pipes may provide growth opportunities for various fungal species. The growth rate and the extent of the growth are directly related to the temperature and other factors such as humidity and nutrient availability.

Molds and their toxins have been implicated in sick building syndrome and specific building-related illnesses. A building-related illness is defined as “a specific, well-defined illness for which a direct building related condition can be shown as the cause.” Sick building syndrome is defined as “a situation where some building occupants experience health and comfort issues associated with being in the building but no specific illness or cause is identified.”

Studies of symptoms and complaints in “sick” buildings frequently identify cold and flu-like symptoms, sore throats, mucous membrane irritation, headaches, diarrhea, and fatigue. However, causally relating these complaints to fungal airborne exposures presents challenges. One is likely to encounter a lack of specific illness association, inability to demonstrate differences in exposure between controls and study subjects, and inadequate study design. Many sick building syndrome studies are actually case reports

or cross-sectional studies, which limit one's ability to draw causal conclusions. There must be a formal causal determination using appropriate scientific methodology, such as epidemiologic criteria (e.g., consistency, strength of association, biologic gradient and temporality) to make a causal connection.

Upon investigation of indoor air quality complaints, one must also consider the possible presence of psychiatric disorders and symptoms (such as somatization disorders, anxiety and depression), allergies, neuropsychological complaints, and the potential existence of secondary gain issues among occupants of the building.

The range of microbiologic diseases includes: influenza, upper respiratory infections, asthma, allergic rhinitis, and humidifier lung (hypersensitivity pneumonitis). However, it is important to remember that in addition to molds, common indoor producers and aggravators of these types of conditions include dust, dust mites, and possible cockroach fragments and excreta.

A high index of suspicion, careful medical testing, and thorough building source identification should be used to determine a diagnosis and whether microbiologics are the source of the complaint.

The presence of mold growth does not mean that a hazardous airborne exposure has occurred. In conducting an allergic mold assessment of building occupants, the type of species of mold found in the building should match the results of skin allergy testing for that specific mold and should be present in the air at significant levels. Timing of symptoms, the presence of other diseases, and appropriate clinical testing may help pinpoint the etiology and possible sources.

While a full range of mold sampling approaches have been used, it is important to use highly qualified and experienced industrial hygiene professionals to ensure accurate assessment of any exposure potential.

As occupational and environmental health is focused on prevention, it is critical that accurate causation assessments be used in regulation and clinical practice. Exposures to molds and mold-produced toxins can be a potential source of significant health problems, especially in individuals who have other health problems that make them particularly susceptible to infection or development of allergic manifestations. However, it is unclear as to the exact role these organisms play in everyday symptoms and complaints in workplaces, schools, and homes. Carefully executed research and appropriate use of scientific and clinical methodology for diagnosis and causal inference will help assure that objectivity is employed in understanding, preventing and managing the health effects of mycotoxins.

Legislative Focus

Developing potential legislation and regulation in the area of mold-associated exposure and potential health effects should be done carefully and based on sound

science. The recent legislation in California points out many problems encountered along the way:

Terms – Somewhere along the line the word mold was transformed into "toxic mold". Such terminology is obviously inflammatory and designed to garner a pre-determined reaction in the general community. Terminology in the area of in –building microbiologics should be based on scientific terms, e.g., mold, fungi, bacteria, etc.

Scope – What microbiologics should be covered? There are over 100,000 mold species. Many have not been shown to have specific toxicity. Others have been shown to be toxic only on certain routes of exposure, i.e., ingestion. Other possible microbiologic exposure concerns such as dampness and bacterial endotoxin exposure have also been correlated with increased symptomatology. Legislation and related regulation should be based on careful toxicologic and epidemiologic assessment as to the type of microbiologic and the route(s) of exposure of concern.

Levels – To date, no scientific and governmental group has determined thresholds of exposure above which specific health risks are of concern. Allergies are rarely dose - related and once an allergy is present, the triggering dose may be much lower than the initial sensitizing dose. If "permissible exposure limits" are established they should be established by specific mold species, chemical by-product, e.g., mycotoxin and related health effect. Additionally, such limits should address whether the levels are for mold growth on objects in open areas, behind closed walls, in basements, attics, etc. versus living areas, or airborne molds/mold by-products.

Hazard Identification and Assessment – If indeed hazard levels can be identified, specific determination of hazard identification, quantification, etc. must be carefully specified. Various types of sampling have been used, although to date, there is a lack of consensus as to what to sample for, and how to sample for it. As in remediation discussed below, who will do sampling and the scientific basis for reliable sampling and laboratory analysis must be also based on sound science and avoidance of financial conflicts of interest, e.g., the remediation contractor should not be related to the hazard identification and assessment contractor.

Education/Notification – Legislation and regulation in occupational and environmental health concerns frequently require information dissemination to consumers, businesses, health care providers, etc. Such information can greatly impact individual well-being, financial transactions, among myriad other areas. Such information must not be cavalierly developed or transmitted. Scientific information should be presented in an unbiased manner. Performance standards may pose real problems and lead to unnecessary litigation due to differences in warning/labeling interpretation. Considering the ubiquity of mold and lack of consensus as to hazardous types and levels of exposure, specific language would potentially have to be somewhat general and that warning and notification may not be very meaningful. For example, a caution statement in a real estate transaction might read: "Five years prior to this sale, there was a leak in the basement of approximately fifteen gallons. A mildew smell

developed and was removed through remediation. The remediation at that time was not certified, as no standards existed. There was no visible microbiological growth in excess of XXX square inches/feet." Or, it could simply say: "Mold has been present in this structure in the past. No visible mold is currently present. Mold can cause allergies and other health effects especially in certain individuals at increased risk due to age, or pre-existing illnesses."

Remediation - Will remediation be based on health risk, symptom/complaint or in some other health/disease manner? What microbiological situations must be corrected and how? Which mold species require remediation? How large does the growth have to be? Does compromise of structural integrity need to be present? Does it have to be airborne? Must "behind wall" growth be addressed and how? Who is qualified to perform remediation? What is a safe level to be achieved through remediation: no airborne mold, no visible mold growth, no mold-related odor? Do personal contents have to be remediated for spores, mycotoxins, MVOCs, etc. and to what extent? All of the above questions are indeed difficult if not impossible to answer with any degree of scientific certainty at the present time.

Monitoring Science – The California law specifically addresses mold standards if they are feasible among other caveats. Staying abreast of scientific and medical publications, governmental studies at the federal and state levels and other advancements in knowledge is essential to assure that all residents, businesses, hospitals, child care facilities, and other groups of concern are adequately protected from clearly-established microbiological hazards. Structuring "blue-ribbon" scientific and medical panels to periodically review and evaluate current knowledge, disseminate state of the art information and propose scientifically-sound recommendations to the legislative and executive branches would serve as an appropriate first step.